IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Roger P. JUNEAU, et al. DATE: March 14, 2007

SERIAL NO.: 10/790,623 GROUP ART UNIT: 2643

FILED: 03/01/2004 EXAMINER: Briney III, Walter F.

FOR: "A SOFT HEARING AID WITH STAINLESS STEEL WIRE"

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DECLARATION OF EDWARD J. DESPORTE UNDER 37 C.F.R. § 1.132
TRAVERSING GROUND OF REJECTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The undersigned hereby declares that he is an inventor of the invention claimed in the above-referenced patent application.

From around 1979 to around 1995 I was a clinical audiologist specializing in hearing aid fittings. From around 1996 to the present I have been Director of Product Development and Quality Assurance at General Hearing Instrument, Inc. I am a co-inventor on a number of ear-worn instrument patents. General Hearing Instrument, Inc. is a member of SoftEar Technologies, L.L.C.

I respectfully submit that it was not obvious to modify the invention shown in our U.S. Patent No. 6,254,526 (Juneau et al. - cited against the claims of the present patent application) when we made the invention claimed in the above-referenced patent application.

The following is a stranded, insulated stainless steel wire historical review.

The SoftEar™ technology (the invention shown in our U.S. Patent No. 6,254,526) was developed in the mid to late 1990s, with a first patent application being filed around December 1997 and the patent application maturing into U.S. Patent No. 6,254,526 being filed in October 1998.

A license agreement was entered into with Siemens Hearing Instruments in around 1999 with the goal of refining the SoftEar technology and bringing that technology into widespread manufacturing. In around 2000, 500 hearing instruments were produced for a Delta Study to access acceptability and reliability of the soft technology. The results of that study revealed that the primary failure mode of the instruments was wire breakage.

Concurrently, SoftEar Technologies, L.L.C. was pursuing an NIH Phase I grant to assess whether a hearing-impaired population would prefer either traditional, acrylic hearing instruments or instruments built with the SoftEar technology if both styles of instruments had identical electronics. That study concluded in around 2001.While 78% of the study group preferred the soft/solid technology (the invention shown in our U.S. Patent No. 6,254,526), an analysis of the repair history of each style of instrument showed higher numbers of repairs of the soft/solid instruments, with wire breakage being the number one failure mode.

To this point, the wire used was the standard for the industry: a 44 gauge stranded copper litz. It was concluded that copper could not withstand the stresses exerted on it in a soft/solid environment. An alternative was pursued.

Our first attempt was to use another alloy in the industry: copper-beryllium. While it did prove stronger than copper, it also proved to be quite rigid. This rigidity caused it to "rasp" its way into the silicone body, and to pull away from the solder joint.

Going out of the general hearing instrument industry, SoftEar investigated the possibility of utilizing stainless steel wire, which was believed to be much stronger than copper and able to withstand the forces that had resulted in failure of the copper wire. We subjected both copper wire and stainless steel wire to cyclical loading, and confirmed that belief.

We then consulted with a wire company, and provided necessary data to them (e.g. resistance

and size data of our copper litz, samples of our copper litz). Our next consideration was conductivity. Gold was considered, but that coating lacked long-term durability when embedded in the soft-solid silicone body of the instrument. After further consultation with wire companies, we opted for a solid steel wire with silver coating. That configuration met our conductivity needs, but proved exceedingly stiff and unsolderable. We pursued a stranded design, which proved very solderable.

The last step was to optimize the insulation. Two forms of Teflon insulation were assessed: polytetrafluoroethelene (PTFE), and ethylene-tetrafluoroethelene (ETFE). Both had many of the same characteristics, but the ETFE proved easier to manage by the technicians.

After more than a year of investigation, trial and error, SoftEar developed a silver-coated, seven-strand stainless steel wire with ETFE (Teflon) insulation.

The undersigned hereby declares that all statements made of his own knowledge are true and that all statements made on information and belief are believed to be true, and that this statement is made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

3-14-2007
Date

Edward J. DESPORTE

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